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PATENT
1199-1-001 CIPIN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT: Moses Rodriguez et al.

SERIAL NO.: 08/692,084

GROUP ART UNIT: Duffy, P.

FILED: August 8, 1996

EXAMINER: 1645

FOR: PROMOTION OF CENTRAL NERVOUS SYSTEM
REMYELINATION USING MONOCLONAL AUTOANTIBODIES#24 2/15/00
T. GrayCERTIFICATE OF MAILING UNDER 37 CFR 1.8

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to the ASSISTANT COMMISSIONER FOR PATENTS, WASHINGTON, DC 20231 on 1/31/00.

Christine E. Dietzel Reg. No. 37,309
(Name of Registered Representative)

John A. Santucci 1/31/00
(Signature and Date)

PETITION FOR EXPUNGE PAPERS IN APPLICATION FILE
UNDER 37 C.F.R. 1.59(b)

ASSISTANT COMMISSIONER FOR PATENTS
BOX AF
WASHINGTON, D.C. 20231

RECEIVED

FEB 04 2000

Dear Sir:

OFFICE OF PETITIONS
DEPUTY A/C PATENTS

It is respectfully requested that papers unintentionally submitted in error with respect to the above-identified Application be expunged from the file and that the proper pendency of this Application be retained.

Specifically, an Amendment and Notice of Appeal, intended to be filed with respect to copending Application U.S.S.N. 08/779,784 on March 1, 1999, were inadvertently and unintentionally filed with the improper heading referring to U.S.S.N. 08/692,084, corresponding to the Instant Application. Applicants respectfully submit that the failure to

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expunge such incorrectly filed papers and obtain their return would cause irreparable harm to the party in interest with respect to the Instant Application on whose behalf the information was unintentionally submitted.

On March 1, 1999 an Amendment and Notice of Appeal, intended to be filed with respect to copending Application U.S.S.N. 08/779,784 ("the '784 Application"), was unintentionally filed with a heading of reference to the Instant Application, U.S.S.N. 08/692,084 ("the Instant Application"). This was recognized and addressed by the filing party, David A. Jackson, Esq. with the Examiner in the '784 Application and a new set of papers were forwarded to the Examiner with respect to the '784 Application.

On March 16, 1999 a Final Office Action was mailed by the Examiner with respect to the Instant Application. On April 2, 1999 an Advisory Action was mailed by the Examiner with respect to the Instant Application and was noted by the undersigned's firm as "erroneous". In the Amendment in response to the March 16, 1999 Final Office Action, filed by Applicants on September 16, 1999, which also included a Notice of Appeal, Applicants made note that an erroneous Advisory Action was received and believed "such Advisory Action was prepared and mailed in error."

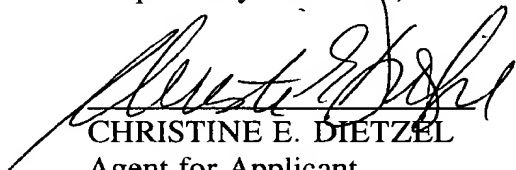
In the Advisory Action mailed on October 20, 1999 with respect to the Instant Application, the Examiner asserted that the Advisory Action mailed April 2, 1999 was not mailed in error, however, on further review she noted that the Amendment and Notice of Appeal addressed claims which were withdrawn from consideration and apparently under consideration in copending Application 08/779,784.

Applicants respectfully petition and request that the Amendment and Notice of Appeal, filed erroneously and unintentionally with respect to the Instant Application be expunged from the file and that the pendency of the Instant Application be retained pursuant to the Notice of Appeal filed September 16, 1999.

The present Petition is accompanied by a check in the amount of \$130.00 to cover the Petition Fee pursuant to § 1.17(i). The Commissioner is further authorized to charge any deficiencies associated with this Petition or credit any overpayment to Deposit Account No. 11-1153. A duplicate copy of this Petition is enclosed for such purpose.

Applicants respectfully request that the petition be granted and that the proper pendency of this Application be retained.

Respectfully submitted,



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In Re: 08/692,084

Attachment to Advisory Action

The amendment after final will not be entered because the amendment to claim 19 would constitute a new search. The amendment to now include HNK-1 as a member of the Markush group in the composition was not previously searched.

Applicants' response has not overcome the enablement rejection for the reasons set forth below.

As to the HNK-1 monoclonal antibody, applicants are claiming the HNK-1 clone. Neither exhibit A nor exhibit B provides for the sale of HNK-1. As to exhibit A, the anti-CD-57 antibodies for sale block the HNK-1 binding, but are not the clone HNK-1, and thus is not persuasive. As to exhibit B, again the antibody cited is "NK-1" and not "HNK-1" as is instantly claimed. Thus, it is not apparent that the clone referenced in the specification and claimed is the same clone which applicants indicates is for public sale. As to Exhibit C, the designation as a distributor is not an indication that the HNK-1 clone is publicly available with unrestricted access by these companies (i.e. for sale). Thus, applicants evidence does not establish the unrestricted publicly availability of the claimed antibody HNK-1. Applicants' have not established that the publicly available antibodies are identical to that monoclonal antibody claimed and cited in the specification as HNK-1.

As to the O1 and O4 monoclonal antibodies. Applicants' evidence does not indicate the public availability of both of these specific monoclonal antibodies. The evidence of record (Exhibit F) Kettenmann et al (Neruosci Lett, 1985, 54(2-3):195-9) teaches that eleven monoclonal antibodies 01-011 were made. However, this does not establish that these particular monoclonal antibodies are publicly available. Exhibit G of Roche Molecular Biochemicals USA establishes a clone 59 which also binds the 01 antigen. Applicants' have not established that clone 59 is identical to the monoclonal 01 antibody of the specification and art and thus have not established the public availability of the monoclonal 01 antibody of the specification. Exhibit G of Roche Molecular Biochemicals USA establishes a clone 81 which also binds the 04 antigen. Exhibit F of Chemicon International Inc. establishes the public availability of monoclonal antibody 345. Applicants' have not established that either clone 59 or MAB345 is identical to the monoclonal 04 antibody of the specification and thus have not established the public availability of the monoclonal 04 antibody of the specification.

Applicants' are claiming specific monoclonal antibodies, the evidence must demonstrate that the claimed monoclonal antibody of the specification is identical to that which is on sale. Deposits are required for specific antibodies because of the events of recombination and affinity maturation lead to unpredictable sequence changes. Thus, for reasons of record, the exact reproduction of a specific antibody is an unpredictable event. Therefore applicants' evidence must show that the antibodies which are publicly available are identical to that which is claimed (i.e. amino acid sequence, structure, and function). Applicants' have not yet met this burden the clones which are on sale are not the antibody 01, 04 or HNK-1 as claimed and recited in the specification.

As to applicants' Exhibit G, exhibit G is not persuasive because it describes the use of isolated and purified polyclonal human IgG or IgM. It does not describe "isolated or synthetic autoantibodies". The art defines an autoantibody as an antibody which is capable of reaction with an antigen which is a normal constituent of the body. In no case has the evidence established that normal serum has autoantibodies as defined by the art. The pooled human IgG and IgM of Exhibit G are not equivalent to "isolated or synthetic autoantibodies". One could not

make and use the instantly claimed isolated or synthetic autoantibodies" for reasons made of record. Evidence demonstrating isolation of pooled human IgG or IgM is not equivalent to that which is now claimed. Moreover, any of the starting materials, methods, procedures and starting materials are not provided for in the specification. The use of pooled human IgG or IgM is not mentioned in the specification and therefore the reliance on methodology known to the art to isolate such is misplaced.

The rejection is maintained.

Applicants' proposed response would obviate the 102(b) is moot since the amendment has not been entered.

All rejections/objections are maintained for reasons made of record.

Applicants' request for clarification of the Advisory Action mailed April 2, 1999. This advisory action was not mailed in error. Applicants' filed an amendment pursuant to 37 CFR 1.116 and a notice of appeal both with a certificate of mailing on March 1, 1999 (see copies attached). These documents crossed in the mail with the final rejection of March 16, 1999 (i.e. the amendment pursuant to 37 CFR 1.116 and a notice of appeal matched after the final rejection had been mailed). Since the amendment was filed under 37 CFR 1.116 at the same time as the notice of appeal, and the claims under consideration had been twice rejected, the notice of appeal was deemed proper and entered into the record. At this point, the record indicated that the response was intended as after final (i.e. filed under 37 CFR 1.116) and the application was "on appeal". Both the proposed amendment and the notice of appeal were correctly identified by serial number, docket number, applicants and examiner. Applicants' have no right of entry of an amendment at the point of appeal. Thus, the after final amendment was properly not entered and an advisory was properly sent because the claims were now under appeal as of the filing date of the notice of appeal in this application.

Upon further review, it is noted that the proposed amendment and notice of appeal addressed claims which were withdrawn from consideration and apparently under consideration in co-pending application 08/779,784. Should applicants believe that these papers of March 1, 1999 were filed in error (i.e. inasmuch as they addressed claims and rejections not under consideration), then they should petition to have them removed from the file in order to retain pendency of this application.

Applicants' now proposed amendment and remarks in regard to the final rejection of 3-16-99 has been addressed, is not entered and not persuasive for reasons made of record above.